

Serial No. 09/679,687

-4-

Docket No. 2119-4266

REMARKS

Claims 25-30, 32, and 34 are pending. No amendments are made in this paper.

Interview Summary

Applicants' representatives thank the Examiners for the courtesy of a telephone interview on February 23, 2006. The claims discussed were 25-30, 32, and 34. The substance of the interview was a discussion of the rejection under 35 U.S.C. § 101 for lack of utility. Agreement with respect to the claims was not reached.

Rejection under 35 U.S.C. § 101

Claims 25-30, 32, and 34 are rejected under 35 U.S.C. § 101 for lack of utility because the "claimed invention is not supported by either a specific and substantial utility or a well-established utility" (Office Action, page 2). Applicants respectfully traverse the rejection.

It is respectfully submitted that this rejection is improper and that the Examiner has not established a *prima facie* case. The claimed invention is supported by at least one specific, substantial, and credible utility or a well-established utility.

To establish that the asserted utility is not specific or substantial, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the application would be specific and substantial. The Utility Examination Guidelines (Federal Register, Vol. 66, No. 4, January 5, 2001) state that:

A patent examiner must accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. The examiner's decision must be supported by a preponderance of all the evidence of record. *In re Detiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the

987843 v1

Serial No. 09/679,687

-5-

Docket No. 2119-4266

Office has sufficient evidence or sound scientific reasoning to rebut such an assertion.
(See, Comment 19.)

In the present case, the specification clearly asserts that Applicants' claimed polynucleotides encode polypeptides having sucrose transport activity, a class of proteins that have a specific, substantial, and credible utility. At best, the Office Action cites general notions that nucleotide or amino acid changes or mutations can alter the function of the biomolecule.

The Patent Office stated:

...However, even if it was demonstrated that SEQ ID NO: 2 is in fact a sucrose transporter, this would not provide the novel sucrose transporter with a specific and substantial utility.

See Office Action dated October 5, 2006, page 4, lines 12-14. This is not the standard required for utility.

With regard to proof of the utility and operability of inventions (other than drugs or other therapeutic inventions) the Patent Office has long applied a rule that an invention is presumed to be operable as disclosed. The burden of proving operability and utility shifts to the applicant only if there is a reasonable doubt as to the truth of the applicant's assertions.

See Chisum on Patents, Volume 1, 4.04[1], page 4-64, 2006 (footnotes omitted).

Evidence submitted to establish usefulness must be such as would be clear and convincing to one of ordinary skill in the particular art.

See Chisum on Patents, Volume 1, 4.04[1], pages 4-68 and 4-69, 2006, citing *In re Ferens*, 417 F.2d 1072, 163 USPQ 609 (CCPA 1969).

We agree that the proofs of utility should be convincing to one skilled in the art, but we cannot agree with the degree of proof required by the Patent Office....The burden the Patent Office would place on appellant would, in effect, require proof beyond a reasonable doubt that the claimed compound possesses the alleged utility.

See Chisum on Patents, Volume 1, 4.04[2][b], pages 4-78 and 4-79, 2006 citing *In re Irons*, 340 F.2d 974, 144 USPQ 351 (CCPA 1965).

987843 v1

Serial No. 09/679,687

-6-

Docket No. 2119-4266

The Examiner's attention is directed to the specification which, contrary to the statements in the Office Action, establishes that the polypeptides encoded by the claimed nucleotide sequences have a specific function assigned (e.g., encode polypeptides having sucrose transport activity). With respect to the nucleotide sequence of SEQ ID NO: 1, the specification at page 1, lines 17-19, provides that:

Specific sucrose carrier sequences from these crop plants should find use in controlling the timing and extent of phenomena such as grain fill duration that are important factors in crop yield and quality.

Polynucleotides of the present invention, such as SEQ ID NO: 1, are also useful, for example, in altering the level of the encoded protein in transformed host cells, see specification page 1, line 37 to page 2, line 5:

In a further embodiment, the instant invention concerns a transformed host cell comprising in its genome a chimeric gene encoding a sucrose transport protein, operably linked to suitable regulatory sequences. Expression of the chimeric gene results in production of altered levels of the encoded protein in the transformed host cell. The transformed host cell can be of eukaryotic or prokaryotic origin, and include cells derived from higher plants and microorganisms. The invention also includes transformed plants that arise from transformed host cells of higher plants...

Indeed, Scofield et al., (Funct. Plant Biol. 29:815-826 (2002), hereinafter, "Scofield", cited in a Supplemental IDS filed with the Supplemental Amendment and Response dated August 5, 2005), show that antisense suppression of the rice sucrose transporter gene, OsSUT1, leads to impaired grain filling. Applicants note that the rice sucrose transporter gene disclosed in Scofield is identical to SEQ ID NO:26 of the pending application and Appendices previously provided with the subject Supplemental Amendment and Response. Prior to Scofield, Hirose et al., (Plant Cell Physiol. 38:1389-1396 (1997), hereinafter, "Hirose", cited previously in the IDS of July 2001 and considered in the Office Action of April 2003), saw high expression levels of

987843 v1

Serial No. 09/679,687

-7-

Docket No. 2119-4266

the rice OsSUT1 in panicles after heading and postulated it was involved in transport of sucrose into the filling grain (see Hirose, page 1395, left column, 2nd paragraph; and Scofield, page 816, column 1)."

Furthermore, the Scofield abstract states:

Many of the plants showed a significant reduction in their ability to produce filled grain, and final grain weight was reduced. Severe phenotypes correlated with a reduction on OsSUT1 transcript level in filling grain.

Accordingly, applicants submit that the claimed invention is supported by a well-established utility as defined in the Examination Guidelines for the Utility Requirement, particularly in response to comment 19, noted above. The claimed invention is directed to polynucleotides that encode polypeptides having sucrose transporter activity. One of ordinary skill in the art would immediately appreciate why the invention (polynucleotides that encode polypeptides having sucrose transporter activity) is useful based on the characteristics of the invention. In addition, the specification provides at least one specific, substantial, and credible utility.

Accordingly, it is submitted that claims 25-30, 32 and 34 have at least one utility that is specific, substantial, and credible, or is well-established. Thus, withdrawal of this rejection is respectfully requested.

Sequence Homology is Appropriate in the Sucrose Transport Art

The Office Action argues that sequence homology is insufficient to show sucrose transport, concluding that Bisson (1993) and Liang are appropriate references in refuting applicants' arguments. However, as noted before, the Bisson reference was published in 1993 and therefore does not represent the state of the art (i.e., 1998). In addition, Liang is directed to glucose transporters and does not represent the state of the art for sucrose transport.

987843 v1

Serial No. 09/679,687

-8-

Docket No. 2119-4266

Contrary to the Office Action's conclusions regarding homology, the skilled artisan in the area of sucrose transporters recognizes that homology is an appropriate means to determine sucrose transport. For example, Aoki states "It is evident that ZmSUT1 is a sucrose transporter from its sequence homology to known transporters" (Aoki, *Plant Cell Physiol.*, page 1075, 1999, right column). Further, the Office Action "concedes that the teachings of Lemoine are more closely directed to the state of the art related to applicants' claimed invention than those of Bisson or Liang" (Office Action, page 4, lines 2-4). Lemoine teaches that following identification of SoSUT1 as the first identified sucrose carrier, "all the subsequently identified carriers have been obtained by hybridisation screening or PCR amplification from these initial sequences," (Lemoine, pages 248-249). Hybridisation screening and PCR amplification are experimental techniques that rely on homology. As shown by Aoki and Lemoine, practitioners in the art of sucrose transport rely on homology both theoretically and experimentally to prove sucrose transport.

Applicants assert that it is well accepted in the art, as evidenced by the Aoki reference, for example, that practitioners in the art of sucrose transport rely on homology both theoretically and experimentally to determine sucrose transport. For these reasons, applicants assert that the utility requirement has been met.

Actual Sucrose Transport Activity

With respect to substrate variability, the Office Action states that the "issue of substrate variability is relevant to utility, because Applicants have not demonstrated that the encoded polypeptide actually has sucrose transport activity" (Office Action, page 3).

The IDS of October 19, 2004 listed Aoki (1999). Examiner Hunnicutt considered Aoki (1999) in the Office Action dated February 4, 2005. Examiner Howard referred to Aoki (1999) in

987843 v1

Serial No. 09/679,687

-9-

Docket No. 2119-4266

the Office Action dated October 5, 2005. The instant application claims benefit of US 60/081,148, filed April 9, 1998. Therefore, Aoki (1999) is not prior art to the instant application.

ZmSUT1, disclosed by Aoki (1999), is within the scope of sequences according to claim 25. ZmSUT1 has 91.5% sequence identity with SEQ ID NO:2, as shown in Appendix B of applicant's response of August 5, 2005. The Office Action concedes the point in stating that the "Examiner agrees that instant SEQ ID NO:2 is 91.5% similar to a maize sucrose transporter taught by Aoki (1999)" (Office Action, page 5). ZmSUT1 is a maize sucrose transporter and shows actual sucrose transport. With respect to claims 26-28, homology to ZmSUT1 is an art-recognized method of determining actual sucrose transport, as discussed in the section above.

With respect to the Examiner's argument that applicants have not shown where instant SEQ ID NO:2 is expressed in the maize plant, such a showing is not necessary. Claim 25 is directed to an isolated polynucleotide, and dependent claims 30, 32, and 34 include a recombinant element such that the claims are not limited to endogenous systems. The polynucleotides can be used with a variety of plant promoter sequences. The specification provides additional information with respect to non-reliance on the endogenous system:

It may also be desirable to reduce or eliminate expression of genes encoding sucrose transport proteins in plants for some applications. In order to accomplish this, a chimeric gene designed for co-suppression of the instant sucrose transport proteins can be constructed by linking a gene or gene fragment encoding a sucrose transport protein to plant promoter sequences. Alternatively, a chimeric gene designed to express antisense RNA for all or part of the instant nucleic acid fragment can be constructed by linking the gene or gene fragment in reverse orientation to plant promoter sequences. Either the co-suppression or antisense chimeric genes could be introduced into plants via transformation wherein expression of the corresponding endogenous genes are reduced or eliminated.

987843 v1

Serial No. 09/679,687

-10-

Docket No. 2119-4266

(Specification, page 12, lines 22-30). Even if a showing of expression pattern was necessary, the Office Action concedes that the expression pattern of the maize sucrose transporter ZmSUT1 is demonstrated in Aoki (1999) (Office Action, page 5, lines 10-11), and ZmSUT1 is within the scope of the claims.

Therefore, where the literature has shown that sequences within the scope of the claims encode polypeptides that have actual sucrose transport activity, the Office Action has failed to cite references from the art of sucrose transport showing why actual sucrose transport would not be credible and specific for polypeptides encoded by the claimed sequences.

Substantial Utility

The Office Action states that "even if it was demonstrated that SEQ ID NO:2 is in fact a sucrose transporter, this would not provide the novel sucrose transporter with a specific and substantial utility" (Office Action, page 4, lines 12-14). Applicants respectfully disagree with this characterization and the implied requirements for utility under the patent law.

The Supreme Court held in *Brenner v. Manson* that the requirements for utility are not met by a process which either has no known use or is useful only "in the sense that it may be an object of scientific research" (*Brenner v. Manson*, 383 U.S. 519, 535 (1966)). In that case, the applicants were attempting to patent a process for the production of steroids with no known use, except for further study. More recently, the Federal Circuit held that claims to expressed sequence tags from maize lacked utility partly because even the applicant "admits that the underlying genes have no known functions," (see *In re Fisher and Lalgudi*, 421 F.3d 1365 (Fed. Cir., 2005)). Further the Federal Circuit held that in using the claimed expressed sequence tags as analytic tools to identify polymorphisms or promoters, "Fisher has not shown that a

Serial No. 09/679,687

-11-

Docket No. 2119-4266

polymorphism or promoter so identified would have a "specific and substantial" use," (*Fisher* at 1373).

Like *Fisher*, the instant claims are directed to polynucleotides. Unlike *Fisher*, the use of nucleic acid fragments of the instant invention to isolate cDNAs and genes encoding homologous proteins from the same or other plant species (as described in the specification at page 10, lines 7-13) would yield targets with real and substantial uses. For example, the Examiner "agrees that Scofield (2002) shows that antisense suppression of the rice sucrose transporter gene, OsSUT1, leads to impaired grain filling," (Office Action, page 5). Since OsSUT1 and SEQ ID NO:2 are approximately 82% homologous, it is a credible and specific utility of SEQ ID NO:2 to use SEQ ID NO:2 in assays for OsSUT1, which has the real-world substantial utility of modulating grain filling in rice.

In addition to assays for OsSUT1, polynucleotides according to the invention such as ZmSUT1 and SEQ ID NO:2 can be used in assays for ZmSUT1, which encodes a sucrose transporter in maize. Therefore, unlike *Brenner* and *Fisher*, the sucrose transporters in rice and maize that can be identified with polynucleotides according to the claims have specific and substantial utility.

In view of the foregoing, polynucleotides according to the claims have a credible, specific and substantial utility, such as assaying for genes with known function. Therefore, Applicants request withdrawal of the rejection of claims 25-30, 32, and 34 under 35 U.S.C. § 101 for lack of utility.

Rejection under 35 U.S.C. § 112, first paragraph

Serial No. 09/679,687

-12-

Docket No. 2119-4266

The Examiner rejects claims 25-30, 32, and 34 for lack of enablement since one skilled in the art would not know how to use the claimed invention in connection with the lack of utility rejection. Applicants respectfully traverse.

Applicants note that the Examiner is limited to 'how to use' the invention in connection with the lack of utility rejection. Applicants refer to the above remarks with respect to utility, and note that numerous references in the art (i.e., Lemoine, Hirose, Scofield, Aoki) refer to the importance of sucrose transport activity and its role for example in grain filling in rice and plant stature in maize. Therefore, Applicants request withdrawal of the rejection of claims 25-30, 32, and 34 under 35 U.S.C. § 112, first paragraph, for lack of enablement with respect to 'how to use' the claimed invention.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application. Applicants respectfully submit that Claims 25-30, 32 and 34 are in condition for allowance. Early notification of the same is earnestly solicited.

Serial No. 09/679,687

-13-

Docket No. 2119-4266

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 2119-4266. A DUPLICATE OF THIS SHEET IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2119-4266. A DUPLICATE OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: April 20, 2006

By: Michael A. Willis

Michael A. Willis
Registration No. 53,913

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
3 World Financial Center
New York, NY 10281-2101
(212) 415-8700 Telephone
(212) 415-8701 Facsimile

Serial No. 09/679,687

-13-

Docket No. 2119-4266

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 2119-4266. A DUPLICATE OF THIS SHEET IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2119-4266. A DUPLICATE OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: April 20, 2006

By: Michael A. Willis

Michael A. Willis
Registration No. 53,913

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
3 World Financial Center
New York, NY 10281-2101
(212) 415-8700 Telephone
(212) 415-8701 Facsimile

987843 v1